REMARKS

Claims 1-6 are pending in the present application. Claim 1 is herein amended. No new matter has been introduced.

Objection to Specification

The specification was objected to because trademarks are not capitalized.

Accordingly, the specification has been amended to capitalize the trademarks. Thus, the objection has been overcome.

Claim Objection

Claim 2 was objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The Examiner alleged as follows:

> The latter part of claim 1 is a "product by process" claim, and it will be examined as a product claim. The MPEP states the following: "[Even though product-by-process claims are limited by and defined by the process determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process ... The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product" (see MPEP 21 1 [R-I]).

Accordingly, claim 1 has been amended to overcome the objection. In the amendment, claim 1 has been amended for clarification to recite: "a hardening component composed of a

derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is modified with an electron-attracting group."

Thus, the latter part of claim 1 has become a non-product-by-process, and claim 2 properly "further limit the subject matter" of claim 1.

Rejections under 35 USC §112, Second Paragraph

Claims 1-6 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As already mentioned, claim 1 has been amended for clarification to recite "a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is modified with an electron-attracting group." Thus, claim 1 has become definite and the rejection has been overcome.

Rejections under 35 USC §112, First Paragraph

Claims 1-6 were rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement.

Regarding the written description requirement, MPEP explains as follows:

> A description requirement issue can arise in a number of different circumstances where it must be determined whether the subject matter of a claim is supported in an application as filed. See MPEP § 2163 for examination guidelines pertaining to the written description requirement. **While a question as to whether a specification provides an adequate written description may arise in the context of an original claim which**

> **is not described sufficiently** (see, e.g., Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)), **there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed.** In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Consequently, **rejection of an original claim for lack of written description should be rare. Most typically, the issue will arise in the following circumstances:**

(MPEP 2163.03, emphasis added). MPEP lists the circumstances: (1) amendment affecting a claim; (2) reliance on filing date of parent application under 35 USC 120; (3) reliance on priority under 35 USC 119; and (4) support for a claim corresponding to a count in an interference.

Thus, a description requirement issue commonly arise when a claim is amended or an application claiming priority of an earlier US application. However, the Examiner rejects the present application as failing to comply with the written description requirement based on allegations such as that the specification does not include description of chemical species and structure, which usually are treated as enablement issues.

Setting aside the appropriateness of the rejection, claim 1 has been amended for clarification to recite "a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is modified with an electron-withdrawing group."

The subject matter claimed in claims 1-6 are sufficiently described in the specification, for example at page 2, line 1 to page 3, line 3, and page 3, line 10 to page 5, line 11.

Therefore, the 35 USC §112, first paragraph rejection should be withdrawn.

Rejections under 35 USC §102(b) over Linden et al.

Claims 1-6 were rejected under 35 USC §102(b) as being anticipated by Linden et al. (U.S. Patent No. 5,634,936).

The Examiner alleged as follows:

> Linden teaches a device for closing off a septal defect including a polymeric self-hardening material in a specific conformation which is delivered directly to a cardiac tissue or into a balloon which spans both surfaces of the defect, and hardened in-situ by change in pH or ionic concentration, organic solvents (see abstract). **Linden teaches biodegradable polymer that are collagen or poly-L-lysine which precipitates above a pH of 3.0. Linden teaches that polymers such as low molecular weight poly-L-lactic acid are soluble in DMSO and would precipitate on replacing the water miscible DMSO with water or saline solutions (see column 6, lines 46-51), meeting the limitation of claims 1-6.** Linden further claims an apparatus for closing off a septal defect (see claims), a plug that meets the limitation of a sealant or blood vessel embolizing material of claim 6.

(Office Action, pages 10-11, item 10).

However, claim 1 has been amended for clarification to recite "a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is chemically modified with an electron-attracting group," which is not a "product by process." Linden does not teach or suggest these recitations.

For at least these reasons, claim 1 patentably distinguishes over Linden et al. Claims 2-6, directly or indirectly depending from claim 1, also patentably distinguish over Linden et al. for at least the same reasons.

Therefore, the 35 USC §102(b) rejection over Linden et al. should be withdrawn.

Rejections under 35 USC §102(b) over Matsuda et al.

Claims 1-3 and 5-6 were rejected under 35 USC §102(b) as being anticipated by Matsuda et al. (JP 09-103479).

The Examiner alleged as follows:

> Matsuda et al teach a less toxic crosslinking method and a medical material formed by this method. The medical material is formed by crosslinking gelatin by succinimidized poly-L-glutamic acid. Matsuda teaches the method of mixing an aqueous solution containing the gelatin and an aqueous solution containing the succinimidized poly-L-glutamic acid and crosslinking the gelatin and the succinimidized poly-L-glutamic acid. Furthermore, the material is a medical material, such as vital adhesive, hemostatic material, embolous material for blood vessel and sealant of aneurysm which is used by direct crosslinking on medical treatment site (see abstract). The working example 1 discloses the method of making the gelling reaction with Poly-L-glutamic acid and gelatin in buffer solution (see paragraph [0006]) and the n-hydroxysuccinimide, poly-L-glutamic acid and a 1-ethyl 3-(3-dimethylaminopropyl) carbodi-imide hydrochloride (EDC) were mixed and melted in DMSO.

(Office Action, page 12, item 15). Matsuda et al. describes as follows:

> This medical material is formed by crosslinking gelatin by succinicimidized poly-L-glutamic acid. This process for producing the medical material comprises mixing an aq. soln. contg. the gelatin and an aq. contg. the succinicimidized poly-L-glutamic acid and crosslinking the gelatin and the succinicimidized poly-L-glutamic acid. The material is a medical material, such as vital adhesive, hemostatic material, embolus material for blood vessel and sealant of aneurysm which is used by direct crosslinking on medical treatment site. The medical material is used by applying the gelatinized gelatin after the crosslinking to either of an adhesion preventive material or drum carrier.

(Matsuda et al., abstract). Another cited portion in Matsuda et al. describes as follows:

> The gelling reaction of the above-mentioned succinimidized poly-L-glutamic acid and gelatin is made for 0.1 to 10 % of the weight of succinimide-ized poly-L-glutamic acid to react at 30-50 -- preferably in addition to 1 to 50 % of the weight of gelatin. The time for reaction is 2

> seconds - about 10 minutes since these are mixed, but it gels in usually 3 to 60 seconds, extremely short time, and such time period will be sufficient. It is preferable to mix these as solutions of both proper concentration because it is easier to obtain uniform gel by doing so. As a solvent for producing this solution, buffer solution, such as a physiological saline, sodium bicarbonate, boric acid, phosphoric acid, etc. besides distilled water, etc. can be used, which is not toxic.

(Matsuda et al., [0006]).

Thus, according to Matsuda et al., gelatin is crosslinked by succinicimidized poly-L-glutamic acid. Poly-L-glutamic acid is not a di- or tri-carboxylic acid of the citric acid cycle. In contrast, di- or tri-carboxylic acid of the citric acid cycle is used in the present invention such as malic acid, oxalacetic acid, citric acid, cis-aconitic acid, 2-ketoglutaric acid.

Thus, Matsuda et al. does not teach or suggest, among other things, "a hardening component composed of a derivative of a di- or tri-carboxylic acid of the citric acid cycle, wherein at least one carboxyl group of the carboxylic acid is chemically modified with an electron-attracting group,"

For at least these reasons, claim 1 patentably distinguishes over Linden et al. Claims 2, 3, 5, and 6, directly or indirectly depending from claim 1, also patentably distinguish over Matsuda et al. for at least the same reasons.

Therefore, the 35 USC §102(b) rejection over Matsuda et al. should be withdrawn.

Double Patenting

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatetnable over claims 4 and 6-7 of copending Application No. 10/527,694 (US 2006/0128948 A1).

Applicants submit herewith a terminal disclaimer. Thus, the rejection has been overcome.

In view of the aforementioned amendments and accompanying remarks, Applicants submit that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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Attachment: Terminal Disclaimer

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